

**United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program**

SOP No: MDP-DATA-01		Page 1 of 7
Title: Data Entry, Record Keeping and Results Reporting		
Revision: 05	Replaces: 03/01/08	Effective: 06/16/08

1. Purpose:

To provide standard procedures to ensure that data and results retained in and reported by laboratories participating in the Microbiological Data Program (MDP) meet minimum reporting requirements.

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program. The procedures and measures required under this SOP must be documented and records must be kept in laboratory logbooks.

3. Outline of Procedure:

Remote Data Entry (RDE) System	5.1
System Access	5.2
Data Entry	5.3
Data Review Requirements	5.4
Data Transmission	5.5
Results Reporting	5.6
Recordkeeping	5.7
Additional Reporting Requirements	5.8

4. References:

- 4.1. SOP MDP-DATA-02, Data Storage and Archival
 - 4.2. SOP MDP-SHIP-03, Procedures for Packaging, Shipping, and Archiving Microbiological Cultures
 - 4.3. Remote Data Entry (RDE) procedures are found in the RDE system's "On-line Help" function and are provided in a User Guide that was distributed to all laboratories.
 - 4.4. MDP Memorandum dated April 13, 2004, Requirement to Notify MPO of Preliminary Positive Findings
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5. Specific Procedures:

5.1. Remote Data Entry (RDE) System

Results for USDA/AMS MDP samples, along with any associated sample set quality assurance (QA) data, shall be reported to the USDA/AMS Monitoring Programs Office (MPO), Manassas, Virginia, following established Remote Data Entry (RDE) procedures.

5.1.1. System Administration

- 5.1.1.1. Each laboratory shall designate an individual or individuals to administer applicable aspects of the RDE system. MPO shall create or modify the RDE account for the designated individual to grant laboratory system administrator privileges.
- 5.1.1.2. The laboratory system administrator shall create RDE user accounts for laboratory personnel using the Maintain User option on the RDE System Admin menu. Each user account shall be assigned one or more roles, which serve as defined permissions to access the different RDE options, based on position requirements.
- 5.1.1.3. The laboratory system administrator shall disable the RDE user account promptly when an individual terminates employment with the organization.
- 5.1.1.4. The laboratory system administrator may reset passwords and unlock accounts as needed using the Maintain User option in the RDE System.

5.2. System Access

- 5.2.1. The RDE system requires a Web browser and an assigned user account and password to gain access.
 - 5.2.2. Laboratory users shall access the secured RDE site by preceding the Web address with “https” for encrypted data communication between the central server and the user’s workstation.
 - 5.2.3. Users within USDA/AMS shall access RDE on the secondary production Web server, which is a protected connection inside the AMS firewall.
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5.2.4. Laboratory users shall access RDE on the alternate, developmental Web server only when the primary, secured site is unavailable.

5.3. Data Entry

- 5.3.1. The laboratory shall create analytical sets, referred to as Groups in RDE, so that samples related to specific QA results are included under one unique Group identification number.
- 5.3.2. Sample identity information shall be entered into RDE if a paper Sample Information Form (SIF) was submitted. A sample shall be attached to a Group in RDE if an electronic SIF was submitted.
- 5.3.3. Analytical data results shall be entered for each sample through the RDE system in the prescribed format.
- 5.3.4. Data may be entered and maintained on a Laboratory Information Management System (LIMS), but shall be imported into the RDE System for sign-off and transmission to MPO.
- 5.3.5. Refer to the latest RDE System documentation for further information. The system documentation is the User's Manual provided by the contractor and any documentation supplied by MPO. System documentation is available on the Extranet.

5.4. Data Review Requirements

- 5.4.1. The data shall go through a multi-level review and sign-off process prior to submission to MPO. The RDE system provides for up to three reviewer sign-offs for each analytical set.
 - 5.4.1.1. Analyst - this first-level sign-off is optional.
 - 5.4.1.2. The Technical Program Manager or designee shall review the data for accuracy and completeness. This sign-off is required by the RDE system before the analytical set is allowed to be transmitted
 - 5.4.1.3. Laboratory Quality Assurance Officer (QAO) or designee shall review the data for integrity of the overall quality system and adherence to MDP criteria. The Quality Assurance Unit (QAU) shall have access to the data and supporting documentation. The QAO sign-off is required.
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5.4.2. Following QAU review of a data package, data may not be changed by any laboratory personnel unless approved by the QAU. Corrections taken shall be documented.

5.5. Data Transmission

5.5.1. Data shall be electronically transmitted to MPO using the Transmit option in the RDE System. Analytical data on any other media shall not be submitted without prior authorization from MPO. Data may be entered and maintained on a Laboratory Information Management System (LIMS), but shall be signed off and transmitted through the Web-based RDE system.

5.5.2. Participating laboratories shall submit electronic results for routine testing to MPO via RDE within 60 days of sample receipt according to established procedures as detailed in this SOP. If the 60 day reporting requirement is not met, the laboratory shall send the MPO Director monthly updates detailing the reason for the delay and a projected schedule for data delivery. If the 60 day reporting requirement is not met **AND** the laboratory does not provide information regarding the reason for the delay and a projected data delivery schedule, MPO will issue a warning letter to the laboratory.

5.6. Results Reporting

5.6.1. Preliminary positive findings

5.6.1.1. Preliminary positive findings are defined in the method SOP for each target organism. Laboratories shall report preliminary positive findings for all target pathogens.

5.6.1.2. Preliminary results shall be emailed to the MPO laboratory liaison(s), with a copy to the Deputy Director. The following elements must be included in the email text: MDP Sample ID number (not internal laboratory ID number), additional identification such as product code (bagged lettuce/spinach), country of origin, grower/packer information, organism, result, and method.

5.6.2. Final results

5.6.2.1. Final results shall be emailed to the MPO laboratory liaison(s), with a copy to the Deputy Director.

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5.6.2.2. Final results shall be emailed to the MPO laboratory liaison(s), with a copy to the Deputy Director. The following elements must be included in the email text: MDP Sample ID number (not internal laboratory ID number), organism, result, and method.

5.7. Recordkeeping

- 5.7.1. Data packages shall be maintained for at least two years following electronic transmission (via RDE) and before applying for disposition to Federal Records Centers as described in SOP MDP-DATA-02. Special consideration shall be granted for early disposition on a case-by-case basis. Supporting documentation generated by MDP participants shall be maintained by the laboratory and may be transferred to a Federal Records Center as described in SOP MDP-DATA-02 after a period of at least two years.
- 5.7.2. Records shall be maintained documenting the custody of samples from collection to final disposition. These records shall show the storage conditions and personnel handling the samples.
- 5.7.3. Records shall be kept regarding sample preparation and analyses, including sample description, storage condition, description of analytical methods, raw data, observations, calculations, and conclusions. The analyst(s) responsible for each segment of a procedure shall be identified in the record.
- 5.7.4. Records regarding shipment of cultures to other laboratories shall be documented as described in SOP MDP-SHIP-03.
- 5.7.5. USDA/AMS MPO will provide the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) with appropriate information semi-annually.
- 5.7.6. Data will be compiled on an annual basis and a summary report released by MPO. Standard USDA/AMS practices to ensure protection of confidential business information will be used when publishing data.

5.8. Additional Reporting Requirements

- 5.8.1. In addition to reporting results to MPO, laboratories shall comply with all State and local reporting guidelines. When a State requests results for a sample or a group of samples that were collected in that State and analyzed by an MDP laboratory in a different State, the results may be released to the collection State.
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6/9/2008

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Revision 05	May 2008	Monitoring Programs Office
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- Revised subsec. 5.6.1.1 to reflect reporting of target pathogens
- Revised subsec. 5.6 to remove Preliminary/Final Results Notification Form (data elements to be emailed to MPO)
- Archived USDA/AMS MDP Preliminary/Final Results Notification Form

Revision 04	February 2008	Monitoring Programs Office
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- Revised data reporting requirement in subsection 5.5.2

Revision 03	May 2006	Monitoring Programs Office
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- Updated RDE procedures
- Revised data review requirements
- Revised data reporting to include use of LIMS
- Added CDC as data recipient
- Updated recordkeeping requirements

Revision 02	November 2004	Monitoring Programs Office
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- Revised to include notification of preliminary and final positive results to MPO, using Attachment 01
 - Added data review requirements and RDE review documentation procedures
 - Revised to accommodate review process done in LIMS rather than RDE.
 - Revised to update references to related SOPs
 - Revised to extend data submission frequency to thirty days.
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